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Subject: Environmental Defense comments on n-phenyl-1-Naphthalenamine (CAS# 90-30-2)

(Submitted via Internet 6/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Cynthia.graham@bayerpolymers.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for n-phenyl-1-Naphthalenamine (CAS# 90-30-2).

The test plan and robust summaries for n-phenyl-1-Naphthalenamine (PANA) were submitted by Bayer Crop Science. PANA, according to the test plan, is used in jet engine lubricants, turbine oils, miscellaneous lubricants and greases, and in polymer syntheses and rubber manufacture.

The test plan claims that there is little opportunity for environmental releases and human exposures, but no information is provided to substantiate this claim. The wide array of uses for PANA seems to indicate that environmental contamination would be likely. We recommend that the sponsor provide any available environmental monitoring data for PANA.

The sponsor concludes that no additional studies are needed to fulfill HPV requirements for SIDS endpoints. The justification for this conclusion is seriously flawed and we disagree with it. In particular, we recommend that the sponsor conduct a combined reproductive/developmental/repeat dose toxicity study and an algal toxicity study.

The algal toxicity studies are needed because no such data exist, and studies on fish and aquatic invertebrate toxicity indicate that PANA is extraordinarily toxic to aquatic organisms. The sponsor states that algal toxicity studies are not needed because PANA is toxic to fish and Daphnia. This seems like an odd justification and is certainly inconsistent with the HPV guidelines. After all, PANA might be even more toxic to algae than it is to fish and aquatic invertebrates.

The reproductive toxicity studies are needed because the sponsor provides no reliable data to indicate otherwise. The test plan states that repeat dose studies are adequate to fulfill requirements for the reproductive and developmental endpoints and that reproductive/developmental studies are not needed because PANA is a carcinogen. This also is an odd justification inconsistent with HPV guidelines. The repeat dose studies referred to are in dogs and mice. However, the dog study was not conducted under GLP, it suffers from significant methodological deficiencies, no information is provided on histological analyses, only three animals were used, no information is provided on gender and no information is provided on any post-exposure period prior to sacrifice. The mouse study was a 2-year cancer bioassay, but no information is provided in the robust summaries on interim sacrifices or histological analyses. Reproductive endpoints need to be assessed in animals that are reproductively capable, and not at the end of a lifetime bioassay. The existing data are not adequate to meet

requirements for the repeat dose, reproductive and developmental endpoints.

Other comments are as follows:

1. PANA is not biodegradable, and this property causes it to be much more toxic to Daphnia after 21 days (LC 50= 0.06 mg/L) than after 48 hrs (LC 50=0.68 mg/L).

2. The 2-year bioassay indicates that PANA causes lung and kidney tumors. It is also indicated in the robust summaries that PANA often contains an impurity (2-naphthylamine) that is classified as a known human carcinogen. What was the level of this impurity in the test substance used for the cancer bioassay?

3. The sponsor concludes that PANA is of low concern as a persistent organic pollutant. What is the evidence in support of this statement, given that PANA is not biodegradable, is extraordinarily toxic to aquatic organisms, is positive in a cancer bioassay, and is contaminated with a known human carcinogen?

4. The test plan and robust summaries state that results are ambiguous for genetic toxicity studies in mouse lymphoma cells and in an unscheduled DNA synthesis experiment. Why are the results ambiguous?

5. Are there any data available on the metabolism of PANA in mammalian systems? Is it readily metabolized and if so, are the metabolites toxic?

Thank you for this opportunity to comment.

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